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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,634	03/15/2002	Michael P. Whitman	11443/72	4140
26646	7590	12/12/2007		
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			EXAMINER SMITH, PHILIP ROBERT	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/099,634	Applicant(s) WHITMAN ET AL.	
	Examiner Philip R. Smith	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-16, 19-21 and 37-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-16, 19-21 and 37-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

- [01] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [02] The rejection of claims 1-3,40-44 as being anticipated by Higuma (654772) set forth in the Office action of 6/1/2007 are withdrawn in view of the amendments of 9/4/2007.

Claim Rejections - 35 USC § 103

- [03] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [04] The rejection of claims 7-9,11-16,19,48-49 as being unpatentable over Higuma (654772) in view of Ishikawa (6071233) as set forth in the Office action of 6/1/2007 are withdrawn in view of the amendments of 9/4/2007.

Additional Claim Rejections - 35 USC § 103

- [05] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [06] Claims 1-2,7-9,11-12,14-16,19,40-43,48-51 are rejected under 35 USC 103(a) as being unpatentable over Noiles (4,576,167) in view of Tsuji (5,402,769).
- [07] With regard to claim 1: Noiles discloses:
- [07a] a flexible shaft, comprising:
- a flexible, elongated outer sheath ("outer shaft tube 60," 13/4);
 - at least one drive shaft ("flexible band 80," 8/45) disposed within the outer sheath;
 - a coupling (comprising elements "234," "235," "30," "78," "264," "260," shown in Figure

11) connected to an endoscope of the outer sheath.

[07b] Noiles does not disclose:

- a moisture sensor disposed within the coupling configured to communicate sensor data corresponding to the presence of moisture within the outer sheath.

[07c] Tsuji discloses a "humidity sensor 22" and a "leakage detecting circuit 24" (4/49) which work in tandem to warn of leakage within an outer shaft of an insertable medical instrument. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include a moisture sensor such as that disclosed by Tsuji in the coupling disclosed by Noiles. A skilled artisan would be motivated to do so in order to enhance reusability by enabling sterilization, a necessary precondition of reusability in surgical instruments.

[08] With regard to claim 2: the outer sheath disclosed by Noiles is autoclavable.

[09] With regard to claim 7: the coupling disclosed by Noiles is configured to detachably couple to a surgical attachment ("anvil assembly 220," 13/40).

[10] With regard to claims 8-9: Noiles discloses that the detachable coupling includes a flexible strip locking mechanism ("retention ring 260," 12/59) for detachably coupling to the outer sheath.

[11] With regard to claim 50: Tsuji discloses that the moisture sensor communicates the sensor data via a data transfer cable (4/48-68).

[12] With regard to claim 51: Tsuji discloses that the moisture sensor comprises a board element ("insulating substrate 51," 5/67), a first lead, and a second lead ("comb-like electrode patterns 52 and 53," 5/66-6/13), the first lead and the second lead printed on the board element, the electrical resistance between the first lead and the second lead varying in accordance with an amount of

moisture present ("humidity-sensitive resistor coating 54," 6/4).

[13] With regard to claim 11: As noted above, Noiles in view of Tsuji discloses

[13a] a flexible shaft, comprising:

- a flexible, elongated outer sheath ("outer shaft tube 60," 13/4);
- at least one flexible drive shaft ("flexible band 80," 8/45) disposed within the outer sheath;
- a coupling (comprising elements "234," "235," "30," "78," "264," "260," shown in Figure 11) connected to a distal end of the outer sheath configured to couple to a surgical attachment ("anvil assembly 220," 13/40); and
- a moisture sensor ("humidity sensor 22" & "leakage detecting circuit 24," 4/49) disposed within the coupling configured to communicate sensor data corresponding to the presence of moisture; and

[14] With regard to claim 12: as noted above, the outer sheath is autoclavable.

[15] With regard to claims 14-16: as noted above, the coupling disclosed by Noiles in view of Tsuji includes a flexible strip locking mechanism (comprising at least "260," as noted above) so that the coupling attaches and detaches to the outer sheath.

[16] With regard to claim 19: as noted above, Noiles in view of Tsuji discloses a moisture sensor configured to detect moisture. At the time of the invention, it would have been obvious to a person of ordinary skill in the art that the moisture sensor be disposed in the coupling disclosed by Noiles. A skilled artisan would be motivated to do so in order to provide leakage detection capability in a sterilizable portion of a surgical instrument.

[17] With regard to claim 40: as noted above, Noiles in view of Tsuji discloses a shaft, comprising an

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elongated outer sheath; at least one drive shaft disposed within the outer sheath; and a moisture sensor disposed a coupling connected to an end within the outer sheath configured to communicate sensor data corresponding to the presence of moisture within the outer sheath.

[18] With regard to claims 41-42: the shaft disclosed by Noiles is rigid and articulable.

[19] With regard to claim 43: as noted above, the outer sheath is autoclavable.

[20] With regard to claims 48-49: as noted above, Noiles in view of Tsuji discloses a coupling detachably connected to an end of the outer sheath, the coupling being configured to detachably couple to a surgical attachment, the detachable coupling including a locking mechanism ("260," as noted above) for detachably coupling to the outer sheath.

Additional Claim Rejections - 35 USC § 103

[21] Claims 37-39 are rejected under 35 USC 103(a) as being unpatentable over Noiles (4,576,167) in view of Tsuji (5,402,769).

[22] With regard to claim 37:

[22a] As noted above, Noiles in view of Tsuji discloses:

- a flexible shaft, comprising: a flexible, elongated outer sheath; at least one drive shaft disposed within the outer sheath;
- a coupling detachably connected to an end of the outer sheath (comprising elements "234," "235," "30," "78," "264," "260," as noted above), the coupling being configured to detachably couple to a surgical attachment ("220," as noted above); and
- a moisture sensor disposed within the coupling configured to detect moisture within the outer sheath.

[22b] Noiles further discloses

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- wherein the coupling includes a connection mechanism configured to detachably couple to the surgical attachment;
- that the coupling includes an engagement shaft including grooves ("threaded distal end portion 234 of rod 30," 13/46);
- a clip ("proximal end 243," 12/65) having flanges ("outwardly projecting lugs 245," 13/1);
- the flanges of the clip configured to engage in longitudinal slits ("L-shaped slots 264," 13/31) of a hollow engagement member;
- the clip configured to receive and secure the engagement shaft in the hollow engagement member, and to frictionally engage with the grooves of the engagement shaft.

[22c] Noiles in view of Tsuji does not disclose

- that the clip having flanges is included in the coupling (clip "243" having flanges "245" is instead included in the surgical attachment "220.");
- that the longitudinal slits are included in a hollow engagement member of the surgical attachment (longitudinal slits "264" are included in a hollow engagement member of the coupling).

[22d] At the time of the invention, it would have been an obvious variation to reverse the disposition of the longitudinal slits with respect to the flanges, such that the longitudinal slits are included in the surgical attachment instead of the coupling, and vice-versa with respect to the clip having flanges. It is clear to a skilled artisan that so long as the flange engages the longitudinal slits, the "anvil assembly 220" may be reliably "mounted on the

distal end of shaft assembly 16" such that "the apparatus is ready for use" (13/59-61).

Additional Claim Rejections - 35 USC § 103

- [23] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [24] Claims 3,13,44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noiles (4,576,167) in view of Tsuji (5,402,769) and in further view of Shimizu (6,099,464).
- [25] With regard to claims 3,13,44: Noiles in view of Tsuji discloses an outer sheath, as noted above. Noiles in view of Tsuji does not disclose that the outer sheath includes a fluoropolymer/silicone material.
- [26] Shimizu discloses "an outer sheath 9a of Teflon (trade name) such as PTFE (polytetrafluoroethylene) or TFE (tetrafluoroethylene)" (6/40-45). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include a fluoropolymer material in the outer sheath disclosed by Noiles in view of Tsuji. A skilled artisan would be motivated to do so in order to construct the outer sheath of a smooth and biologically inert material. Fluoropolymer has these well-known properties.

Additional Claim Rejections - 35 USC § 103

- [27] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [28] Claims 4-6,20-21,45-47 are rejected under 35 USC 103(a) as being unpatentable over Noiles (4,576,167) in view of Tsuji (5,402,769) and in further view of Yabe (4,654,701).
- [29] With regard to claims 4,20,45:
- [29a] Noiles in view of Tsuji discloses:

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- a coupling (comprising elements "234," "235," "30," "78," "264," "260," as noted above) connected to an end of an outer sheath.

[29b] Noiles in view of Tsuji does not disclose:

- a memory unit disposed in the coupling.

[29c] Yabe discloses

- a "RAM 22" in which "examination serial number (data D1), patient's name (data D2), patient's number (data D3) and examination date (data D4) are keyed in or read out of a card in [an] input device 16 and stored in respective memory areas" (2/23-45).

[29d] At the time of the invention, it would have been obvious to a person of ordinary skill in the art to store data including at least one of serial number data, identification data and usage data in a random access memory in instrument disclosed by Noiles in view of Tsuji. A skilled artisan would be motivated to do so in order to coordinate surgical data with patient information.

[30] With regard to claim 5,21,46: as noted above, Yabe discloses that the memory unit stores data including at least one of serial number data, identification data and usage data.

[31] With regard to claim 6,47: Yabe discloses a data transfer cable disposed within the outer sheath, wherein the memory unit is logically and electrically connected to a data transfer cable.

Response to Arguments

[32] Applicant's arguments have been considered but are not persuasive. Applicant contends that "the sensor 22 of Tsuji is not located 'within the coupling' as recited". The new rejection reflects this amendment. It is held that the motivation to detect humidity within a sterilizable instrument is as readily applied to a "coupling" at a distal end of an outer shaft as it is to the outer shaft itself.

[33] Applicant further contends that Noiles teaches away from sterilization.

[33a] It is maintained that making the instrument of Noiles sterilizable does not render the reference unsatisfactory for its most basic intended purpose, i.e. surgical stapling. Noiles is primarily concerned with an effective stapler (1/6-10), and secondarily concerned a design which is easily and cheaply manufactured (2/6-8):

For an instrument to be economically disposable after use in only one surgical procedure, however, the cost of the instrument must be relatively low. This generally dictates that as much as possible of the instrument be made of inexpensive materials such as plastics, and that the instrument have the simplest and lightest possible construction.

[33b] Therefore, disposability is a luxury made possible by low-cost manufacture. If an operator decides to sterilize and reuse Noiles' stapler, there is not a single component which would fail to operate as intended. Noiles does not "teach away" from sterilization; he merely suggests that his invention can be manufactured inexpensively.

Conclusion

[34] Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

[35] A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the

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mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

- [36] Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R. Smith whose telephone number is (571) 272 6087 and whose email address is philip.smith@uspto.gov. The examiner can normally be reached between 9:00am and 5:00pm.
- [37] If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272 4764.
- [38] Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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